

ROLE AND RESPONSIBILITIES OF NOMINEES OF CPCSEA

PART A

DOs AND DON'Ts FOR NOMINEES

The primary responsibility of a person who has been nominated to represent the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) on an Institutional Animal Ethics Committee (IAEC) is the well being and welfare of the animals housed or kept for experiments / breeding. With this in mind, the nominee should be familiar with the rules governing housing, experiments and after care of the animals. It is also imperative that the nominee upholds the dignity of the CPCSEA at all times.

1. Ensure that meeting notices and associated papers sent by the Institution on which IAEC the nominee is a member are carefully read and understood. All Institutions are requested that papers should be sent to IAEC members before 20-30 days (depending on bulk) to allow reasonable time for the concerned to go through the papers and make suggestions/ recommendations at the meeting.
Go through the protocol of the experiment/ proposals and if in doubt regarding the justification for the experiment and whether it could be carried out using smaller or a lesser number of animals, please raise the issue in IAEC meeting and clarify. Any protocol which uses animals other than guinea pigs, rabbits, rats, mice, hamsters and invertebrate animals should be first cleared by the IAEC and then sent to CPCSEA for clearance.
2. During the meeting,
 - a) The nominee should be polite, yet ensure that the points raised are taken note of.
 - b) Do not allow yourself to be intimidated by the others.
 - c) Ask for clarifications to make an informed decision on points discussed.
3. In the best interests of animals it is important that the nominee secures the co-operation of the other members of the IAEC by persuasion, rather than by confrontation. To do this, it would be helpful for the nominee to collect as much information as possible on the subject and familiarize himself/ herself with the kind of experiments being carried out at the laboratory – for example, if regulatory law for a chemical requires its mandatory testing on six animals, it is futile for the nominee to argue that four would be sufficient.
4. Since feeding and watering of the animals must be provided for during non-working hours as well as on holidays, the nominees should check the animal houses at such times whenever possible. No prior intimation is required as per rules (PCA Act, 1960).

WHAT TO LOOK FOR IN ANIMAL HOUSES

An animal which grows and behaves normally and is free of disease is usually considered to be in a state of “Well Being”. All aspects of Animal care should be directed towards the achievement and preservation of this state.

- A. Housing : Location and space requirement, type of cages, material, environment.
- B. Feed : Feeding Schedule, type of diet.
- C. Water : Clean sterile water, type of bottle, nozzle.
- D. Exercise : Inside the cage if it is large enough –otherwise in open space, especially for large animals.
- E. Health : Diseases, health checkup records
- F. Handling : Whether personnel are trained?
- G. Companionship : Do they provide companionship of compatible members of the same species? Solitary confinement is not recommended except in specific cases.

PART B

EQUIP YOURSELF

As a nominee of the CPCSEA it is important that you believe in yourself, be proud to serve this noble cause and develop the confidence to do so. In ‘Equip Yourself’ the norms of the CPCSEA and finer details of animal experimentation which need to be adhered to by the Institute / Establishment is spelt out in three parts – (1) Documentation (2) Status of Animal House (3) Useful hints for an IAEC meeting.

1. DOCUMENTATION

1. Ensure that all ongoing projects and projects to be implemented have been represented and documented in ‘Form B’ (‘Form B’ comprises of Para A; Part B for experiments using animals other than non-human primates and Part C for experiments using non-human primates).
2. Ensure that the ‘Form B’ is duly filled, all details provided and carries the signature of the investigator with date.
3. Only projects that involve small laboratory bred animals (i.e., guinea-pigs, rabbits, rats, mice, hamsters and invertebrate animals) come under the purview of the IAEC. All other projects have to be necessarily sent to CPCSEA for further scrutiny after approval of IAEC.
4. Carefully scrutinize and study the filled in ‘Form B’. Be specially attentive to details regarding –
 - i. Number of animals used.
 - ii. Species used, breed in case of dogs and genus in case of primates.
 - iii. Whether contract/collaborative research.
 - iv. Who is the funding agency.
 - v. Substance tested.
 - vi. Name of client for whom the test/ experiment is being conducted.

- vii. Method of euthanasia (Annexure 1)
- viii. Scrutinize 'Form C' – Check for any discrepancies regarding number of animals declared and number of animals in the animal house. Do a physical count.
- ix. Scrutinize 'Form D' – check for any discrepancies. Cross check with other available documents such as animal house records.
- x. If animals are not sacrificed after the experiment, what happens to them? Will rehabilitation be necessary?

In case of Breeder :

- 1. Scrutinize documents – i.e., 'Form A' and 'Form C' ('Form B' and 'Form D' are not applicable)

2. STATUS OF ANIMAL HOUSE

On visiting the animal house ensure that experimental animals are treated well and attended more often than non-experimental animals. Hence as a CPCSEA nominee, you may rescue the animals or relieve their trauma.

Inspect/ensure for the following:

- 1. Animals should be located in a quiet atmosphere, undisturbed by traffic.
- 2. Premises should be kept tidy and hygienic conditions to be maintained.
- 3. Animals should be protected from drought and extremes of weather and suitable bedding provided.
- 4. Animal cages for small animals and stables for large animals should be in such a way that the animal lives in comfort and overcrowding is avoided.
- 5. Enrichment of environment and provision for socializing.
- 6. Method of housing – ensure excreta of one cage does not enter other cages.
- 7. Animal attendants should be suitably trained and experienced in handling animals.
- 8. Arrangements for feeding and care of animals are made for holidays/weekends/emergencies.
- 9. Only trained persons should be allowed to carry out the experiments.

3. USEFUL HINTS FOR AN IAEC MEETING

- 1. Ensure that a study requires the use of animals. Mandatory use of animals arise in the case of regulatory testing of pharmaceuticals, cosmetics and immuno- biologicals.
- 2. If alternatives are available in the case of fundamental/ basic research, it may be emphasized to follow. Check whether the study is repetitive.
- 3. See if the number of animals used be reduced.

PART C

EUTHANASIA METHODS NOT ACCEPTABLE FOR ANY SPECIES OF ANIMALS.

a) PHYSICAL METHODS

- i) Decompression
- ii) Stunning

b) INHALATION OF GASES

- i) Nitrogen Flushing
- ii) Argon Flushing

c) DRUG ADMINISTRATION

- i) Curariform drugs
- ii) Nicotine Sulphate
- iii) Magnesium Sulphate
- iv) Potassium Chloride
- v) Strychnine
- vi) Paraquat
- vii) Dichlorvos
- viii) Air embolism

It is strongly recommended that an over dose of Thiopentone Sodium be used for euthanasia of all species, except under very exceptional cases.

PART D

ROLE OF NOMINEE

- 1) Nominee should be familiar with the CPCSEA guidelines, the concept of 4Rs and other animal welfare issues. He/She must keep liaison with CPCSEA and also browse the MoEF website for any update of information or draft guidelines or rules and regulation, placed for comment. He/She should be familiar with animal experimentation procedures, husbandry conditions, supplies, humane way of dealing with animals, handling procedures etc and other requirements as published in the CPCSEA/INSA guidelines. He/she must learn/be familiar with alternatives, reduction and refinement procedure available in biomedical research studies/programmes.
- 2) Nominee attached to educational institution should be through with the syllabus prescribed by the University/college for a particular course. Nominee attached with research institutions should learn about the overall goal/mandate of the institute and keep himself/herself abreast with the current and past work done by the institute in animal studies and thus be able to link the new studies proposed. Nominees attached with institutions undertaking regulatory toxicology work should read and be familiar with various guidelines for registration of products such a pesticide, drugs and pharmacology, biotechnology etc. For any clarifications on the protocols, methods, either they should see more details with the investigator when the agenda is circulated or seek comments from CPCSEA.

- 3) Nominee must read the proposal attached with Agenda thoroughly and come prepared to attend the IAEC meeting. He/she should aim for humane/ethical issues related to experiments, avoidance of repetitions of animal studies, numbers of animals used and possible reduction without losing scientific conclusions etc.
- 4) Nominee should not to indulge in arguments and heated debate but understand the merit of a study based on above principles.
- 5) Nominee is expected to sign the necessary forms of each protocol and maintain a copy/list in his/her records.
- 6) In case of proposals dealing with large animal, nominees should note that IAEC is only a recommending authority for such studies. Nominee should ascertain the capability of institution to perform studies on large animals and make sure his/her recommendations find place in the minutes attached to CPCSEA.
- 7) If meetings are not held for 6 months in a row because of lack of projects or due to other reasons, nominee should notify to CPCSEA about “no meetings” after confirmation/verification with the organization.
- 8) Nominee should visit animal house at least once in a calendar year to look at the well being and maintenance of animal and relevant record books and submit the annual report in the prescribed annual report format to CPCSEA office within a month from the date of inspection.
- 9) The nominee would be paid sitting fee and reimbursement of travel expenditure by the establishment / institute as determined by CPCSEA, from time to time.

What are the things a Nominee is not supposed to do

1. Nominee should not decide the merit and demerit of any specific research but he should ensure that experiments are performed in humane manner with minimum suffering to animals and minimum possible use of animals. [Note: Subject Experts in funding agencies decide the merit of research].
2. Nominee is not allowed to print visiting cards, letter heads with his/her name with Government of India official seal as IAEC nominee.
3. Nominee is not permitted to make any campaign/publicity about his/her role and solicit any sponsorship from any organization falling under his/her jurisdiction.
4. Nominee should not sign the minutes of the meeting/Forms/Register without attending the meeting in person.

5. Nominees should not allow any tele/audio conference with a non-participating member during the IAEC meeting.
6. Nominee should not allow any outside member to attend the IAEC meeting.
7. The nominees must keep themselves away from the media and press and will not disclose the confidential information related to the institution they are attached with or the CPCSEA.
8. Although all the nominees are very accomplished and dignified, Nominees are requested to abstain from entertaining any kind of favour in cash or kind other than sitting fee. Institutions have right to complain against a nominee, if the nominee exceeds his/her limit considering himself/herself as authority of licensing or passing any inspection etc. Since several nominees also belong to some research institution, they may appreciate this clarity of communication.
9. It is responsibility of the nominee to be truthful in evaluation and reporting and he/she should not challenge or threaten any organization. In nutshell, a nominee should feel graceful in having recognised by CPCSEA as a responsible person to guide and upgrade quality of researchers and institutions and he should not feel that he is empowered by CPCSEA to take actions or decisions. His role is to report the discrepancy, if any, to CPCSEA.